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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,215	07/30/2001	Jean Francois Michelet	P66893US0	8358

7590

07/14/2004

JACOBSON HOLMAN
PROFESSIONAL LIMITED LIABILITY COMPANY
400 SEVENTH STREET, N.W.
WASHINGTON, DC 20004

EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,215

Applicant(s)

MICHELET ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Amendment filed on February 13, 2004. Claims 1-26 are pending. Claim rejection under 35 U.S.C. § 112, first paragraph is maintained in part and withdrawn in part.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-26 are rejected for lack of written description. While the specification recites using "EP-3 receptor antagonist", there is no disclosure as to what compounds are actually used for the claimed invention. It is noted that specification on p. 4, first full paragraph that applicants teach "the non-prostanoid antagonist L789106" as an example of an EP-3 receptor antagonist. However, while applicants disclose this single example of an EP-3 receptor antagonist, there is no teaching in the specification that this is what applicants are actually using in the invention or what the EP-3 receptor antagonists are in fact effective for the claimed method. Applicants define in the specification p. 6, last paragraph, the expression "prostaglandin EP-3 receptor

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antagonist" as "antagonist compounds which make it possible to attenuate, reduce or stop the loss of head hair and other hairs". Examiner views that this definition does not convey to a skilled artisan that applicants in fact had in possession the specific prostaglandin EP-3 receptor antagonist useful for the claimed effect. Examiner notes that the example formulations in the specification merely shows using "prostaglandin EP-3 receptor antagonist", and does not disclose what compounds applicants are actually employing in the formula.

Similarly, while claim 18 recites using prostaglandin EP-2 receptor agonist and prostaglandin EP-4 receptor agonist, applicants do not disclose what actual compounds are used in the invention, or what the scope of the limitation is.

Response to Arguments

Applicant's arguments filed on February 13, 2004 have been fully considered but they are not persuasive.

Applicants argue that several agonists and antagonists of EP receptors are "described" in Narumiya reference, and examiner agrees. However, the issue here is not whether the EP receptors are known to the scientific community; the relevant issue is whether, the applicants' specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of all EP-3 receptor antagonist as claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination

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reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

An applicant's disclosure obligation varies according to the art to which the invention pertains. See, e.g., *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992). For inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. Disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention. See, e.g., *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021 ("A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. **It is not sufficient to define it solely by its principal biological property**, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.”) (emphasis inserted) In such instances the alleged conception fails not merely because the field is unpredictable or because of the general uncertainty surrounding experimental sciences, but because the conception is incomplete due to factual uncertainty that undermines the specificity of the inventor’s idea of the invention. *Burroughs Wellcome Co. v. Barr Laboratories Inc.*, 40 F.3d 1223, 1229, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994).

In this case, examiner views that the conception of the present invention is not clear because the disclosure does not show, even in the example formulations, what actual compounds are actually used or have efficacy to the claimed methods, and also because of factual uncertainty that undermines the specificity of the inventor’s idea of the invention. Applicants describe in general definition of an agonist and antagonist in the specification in spec. p. 6. The definition of the claimed EP-3 receptor antagonists is however limited to the allegedly discovered function of the compounds, i.e., “antagonist compounds which make it possible to attenuate, reduce, or stop the growth of hair”. The court in *Amgen* held that description is insufficient where applicants describe the compound merely by its biological function. In fact, even applicants’ current position is inconsistent with the disclosure in the specification and the teaching in the *Narumiya* reference: applicants assert sulprostone, which is otherwise known as an EP-3 receptor agonist, is an EP-3 receptor antagonist.

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To support the position that EP receptors are well known to one of ordinary skill in the art, applicants refer to the Kiriya report of binding affinities of mouse prostanoid receptors to several prostanoids and their analogs. However, examiner views that more evidence is necessary to show that applicants had the possession of the claimed invention of a composition comprising EP-3 receptor antagonists, EP-2 and EP4 receptor agonists, and the method of use such composition to inhibit hair growth because identifying such prostanoid receptor agonists and antagonists is viewed an emerging and unpredictable technology. The reference teaches, "different degrees of responsiveness of the same receptor type in different specie". The Narumiya article in fact states that the analysis of K1 (inhibitory constant) values and their analogs "are not available for the receptors from other species", and similar inhibitory constant value have been shown or can be calculated for some of the human receptors. See p. 1204, first col., bridging par. Furthermore, It is viewed that this analysis does not show what applicants had in their possession at the time of the invention. While the Narumiya reference does teach limited number of angonists and antagonists, neither this limited teaching shows what EP-3 receptor agonists applicants had and used in the claimed invention at the time of the invention.

In conclusion, examiner views that the specification insufficiently describes the invention because the level of skill and knowledge in the art does not identify EP-3 receptor antagonists, there is no known structure or physical properties other than its general biological properties, there no known correlation between structure and function, or method of making the claimed invention. It is viewed that applicants'

disclosure fails to reasonably convey a skilled artisan that at the time of the invention applicants had the possession of the claimed composition and method.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER